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THE PATENT OFFICE
- 6 JUN 2003
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1/77
03JUN03 E816258-1 000284
P01/7700 0.00-0313137.2

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
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NP10 8QQ

1. Your reference

HL85591/000/ASG

2. Patent application number
(The Patent Office will fill in this part)

0313137.2

- 6 JUN 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

BIOMET MERCK LIMITED
Waterton Industrial Estate
Bridgend
South Glamorgan CF31 3XA

Patents ADP number *(if you know it)*

8534570001

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

4. Title of the invention

SURGICAL DEVICE

5. Name of your agent *(if you have one)*

Haseltine Lake

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Imperial House
15-19 Kingsway
London
WC2B 6UD

Patents ADP number *(if you know it)*

34001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	-
Description	10
Claim(s)	3
Abstract	1
Drawing(s)	1

10. If you are also filing any of the following, state how many against each item.

Priority documents	-
Translations of priority documents	-
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	-
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	-
Any other documents *(please specify)*	-

11. I/We request the grant of a patent on the basis of this application.

Signature — Date: 6 June 2003

12. Name and daytime telephone number of person to contact in the United Kingdom: Mr A S Giles [0117] 910 3200

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Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.*

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SURGICAL DEVICE

This invention relates to a surgical device and particularly relates to a device having two main components which are interconnected by a "snap-fit" connection.

BACKGROUND TO THE INVENTION

The goal of hip reconstruction is to attempt to reproduce the normal kinematics of the hip by recreating the functional geometry of the acetabulum and proximal femur. This greatly influences the outcome of the operation, restoring normal muscle function, gait and ultimately the longevity of the implant.

In conventional replacement hip surgery a femoral component is inserted into the prepared femur. The femoral component has a stem portion which projects into the femoral canal of the prepared femur and has an integral or separate modular head of substantially spherical shape. The ball-like head of the femoral component is received within an acetabular cup component which is implanted in the patient's hip socket, ie the acetabulum. The acetabular cup has a substantially hemi-spherical bearing surface for movement of the ball head of the femoral component during action of the joint. The acetabular cup is implanted into the prepared hip socket either with or without cement. Cementless types of acetabular cup may be secured in the prepared bone by a press fit or can be directly screwed in place or otherwise secured in place, for example by indirect means, eg by the use of

separate bone screws passing through apertures provided in the acetabular cup. Generally, the femoral stem is of metal and the ball head is of metal or of a ceramic material.

In some designs of hip prostheses the material of the bearing surface of the acetabular cup, is of the same material as that of the ball head, eg for a ceramic head a ceramic bearing surface is provided (a so-called ceramic-on-ceramic prosthesis) and for a metal head a metal bearing surface is provided (a so-called metal-on-metal prosthesis). In some other designs, the acetabular bearing surface is of polyethylene and the acetabular cup is either provided with a polyethylene inner liner or the acetabular cup is a single component made entirely from polyethylene.

The connection between the femoral stem and the femur may be cemented or cementless. Depending on which type of connection is used, an appropriate broach and/or file is used to enlarge the femoral canal. For a cementless connection, the file is of substantially the same dimensions as the femoral stem which is to be implanted, whereas if the connection is cemented, the file is slightly oversized relative to the femoral stem. Once the femoral canal has been enlarged sufficiently to accommodate it, the femoral stem is implanted. Then a series of trial femoral heads, which have bearing surfaces offset laterally and/or displaced relative to the femoral stem to differing degrees, are attached to the femoral stem. This "trial reduction" procedure is used to select the most appropriate femoral head for a particular patient.

The applicant uses a modified procedure in which the broach or file itself, rather than the actual femoral stem, is used with a variety of trial femoral heads in a trial reduction procedure. This allows the surgeon to assess stability of the joint and leg length, prior to selecting the definitive implant.

The surgeon has two methods of altering stability and leg length. A range of neck lengths are available for the modular femoral head which can move the head centre either longer or shorter than the standard zero position, this will increase or decrease femoral offset and thus alter tissue tension, stability, but at the same time will also affect leg length. The second method is to use an increased offset stem, which will increase tissue tension by lateralising the femur, without increasing leg length. With this system, both methods can be assessed at the trial reduction stage.

In all of these conventional techniques, the interconnection between the femoral head and the femoral stem (or the broach or file in the case of the applicant's existing procedure) comprises a pin formed on the femoral stem, file or broach and a corresponding socket formed on the femoral head. This arrangement provides good lateral alignment, but does not prevent displacement of the femoral head along a longitudinal axis of the femoral stem, broach or file. This "pistoning" effect makes it more difficult to select an appropriate femoral head and tends to complicate the trial reduction procedure.

STATEMENTS OF INVENTION

According to a first aspect of the present invention there is provided a surgical device comprising a first portion and a second portion, the first and second portions being releasably connected together by means of cooperating first and second formations, the second formation comprising a resilient arm on the second portion which engages the first formation on the first portion.

Preferably, the first formation is integrally formed with the first portion.

Preferably, the first formation comprises a recess or projection.

Preferably, the second formation is integrally formed with the second portion. It is particularly advantageous to form the first formation integrally with the first portion and/or the second formation with the second portion, because the less components there are in a surgical tool, the easier it is to sterilise. Indeed, it will be appreciated that by forming the cooperating formations integrally with the first and second portions, the number of separate components is reduced to a minimum and the surgical tool is particularly easy to sterilise.

Preferably, a recess or projection is formed on the resilient arm and engages the first formation. Preferably the recess or projection is formed at a free end of the resilient arm.

Preferably, the second portion is at least partially bifurcated.

Preferably, the resilient arm forms a fork of the bifurcated part of the second portion. Preferably, the first formation is received between forks of the bifurcated part of the second portion.

Preferably, the first portion is provided with a first planar guide surface which engages a second planar guide surface on the second portion.

Preferably, an abutment is provided, for example on the first or second planar guide surface, which abutment limits the relative movement between the first and second portions.

Preferably, the first portion is adapted to connect, one at a time, to a plurality of alternative second portions.

The surgical device may comprises a hip prosthesis for replacing a head of a femur. The first portion preferably comprises the stem of the prosthesis, and the second portion is the same shape as a neck of the prosthesis. Preferably, the second portion is adapted to receive a prosthetic femoral head.

Alternatively, the first formation comprises a surgical tool. The second portion may comprise a detachable handle. Preferably, the first portion comprises a drill bit, broach, file or rasp.

Preferably, the first portion comprises an annular ridge formed around the circumference of the surgical tool. Preferably, the resilient arm is biased radially inwardly towards the surgical tool and may engage over the ridge.

Preferably, the resilient arm is arcuate and curves at least partially around the circumference of the surgical tool.

A method of attaching a first portion of a surgical device to a second portion of a surgical device, the surgical device having the features of one or more of the preceding aspects of the present invention, the first portion comprising an elongate member defining a longitudinal axis and the first formation being provided on a distal end of the first portion, the interconnection between the first and second formations being made by sliding the second portion towards the first formation in a direction substantially perpendicular to the longitudinal axis of the first portion.

Preferably, the second portion comprises an adaptor to which a plurality of alternative femoral heads can be connected. In an alternative embodiment, a plurality of adaptors of different lengths and/or shapes may be provided for use with alternative femoral heads, or a common femoral head, such that adjustment of the femoral head relative to the femoral stem is provided by the adaptor, rather than, or as well as, by the femoral head itself.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show more clearly how it may be carried into effect, reference will now be made, by way of example, to the accompanying drawings, in which:-

Figure 1 shows a femoral file, adaptor and trial femoral head in an assembled condition; and

Figure 2 shows an adaptor and trial femoral head in a disassembled condition.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Figures 1 and 2 illustrate a surgical device comprising a femoral broach or file 2 comprising a file portion or stem 4 which tapers outwardly towards an enlarged fixing portion 6. An adaptor 8 is connected to the fixing portion 6 by means of cooperating formations 10, 12. The adaptor 8 is provided with a shaft 14 which tapers towards a free end 16 of the adaptor 8. A trial femoral head 18, having a socket 20 which tapers inwardly towards its base, is received closely on the shaft 14.

A planar guide surface 22 is formed on the adaptor 8 and rests on a corresponding planar guide surface 24 formed on the fixing portion 6 of the femoral file 2.

The second formation 12 is integrally formed with the adaptor 8 and comprises a resilient arm having, at its free end, a projection 26. The adaptor 8 is bifurcated

at its end opposite to free end 16, such that the resilient arm comprises a first fork, and the portion 28 of the adaptor 8, on which is formed the planar guide surface 22, comprises the second fork. A recess 30 is defined between the resilient arm and the portion 28. An abutment 29 is formed on the adaptor 8 and projects into the recess 30.

The first formation 10 comprises a projection with a sloping leading surface 32 and a ridge 34 which is formed in an end surface of the fixing portion 6.

During an operation to install a prosthetic hip joint, the proximal end of the femur is prepared and the femoral canal is enlarged by means of the broach or file 2. When the broach or file is being used to enlarge the femoral canal a handle (not shown) is attached to the fixing portion 6.

When the required dimensions of the femoral canal have been achieved, the file 2 is left in place and the handle is detached. The adaptor 8 is then offered up to the file 2, such that the planar guide surface 22 rests on the planar guide surface 24 of the file 2 and the first formation 10 is received in a mouth of the recess 30. The adaptor 8 is then pushed in the direction A towards the first formation 10, so that the projection 26 rides up the leading surface 32 and drops into the ridge 34. At this instant, a leading edge of the first formation 10 comes into contact with the abutment 29, so that the adaptor 8 is firmly connected to the file 2. A trial reduction can then be carried out by offering up various trial femoral heads 18 have different offsets or having sockets 20 of different

depths until an appropriate femoral head has been selected.

Finally, the file 2 is removed from the femoral canal and an appropriate femoral prosthesis is assembled with the selected femoral head and implanted into the femur.

In an alternative embodiment not illustrated, a plurality of alternative trial adaptors 8 are provided, which may for example have different lengths of shaft 14. An appropriate adaptor 8 may then be selected either for use with a common femoral head 18, or for use with one of a plurality of different femoral heads. During the trial reduction, the easy interconnection of each adaptor 8 with the file 2, simply by means of pushing the cooperating formations 10, 12 together to make the connection and pulling them apart to break the connection, enables rapid selection of an appropriate adaptor.

It is readily apparent that as the formation 10 is integrally formed with the file 2 and the resilient arm 12 is integrally formed with the adaptor 8, the overall number of components are minimised and the surgical device as a whole is very easy to sterilise.

The fixing portion 6 of the file 2 and the bifurcated region of the adaptor 8 can be made using a variety of known techniques. However, it has been found particularly advantageous to cut these components from solid blocks of material using a hot wire cutter.

Various materials can be used to form the adaptor 8, such that the resilient arm 12 has sufficient

resilience to be repeatedly connected to and disconnected from the file 2. It had been thought that stainless steel would be insufficiently compliant and would fatigue excessively. However, the applicant has discovered that Custom (registered trade mark) 455 stainless steel and Aubert & Duval X15TN stainless steel are particularly good materials for use with a surgical device in accordance with the present invention.

CLAIMS

1. A surgical device comprising a first portion and a second portion, the first and second portions being releasably connected together by means of cooperating first and second formations, the first formation being attached to the first portion and the second formation comprising a resilient arm which is attached to the second portion and engages the first formation on the first portion.

2. A surgical device as claimed in claim 1, in which the first formation is integrally formed with the first portion.

3. A surgical device as claimed in claim 1 or 2, in which the first formation comprises a recess or projection.

4. A surgical device as claimed in any one of the preceding claims, in which the second formation is integrally formed with the second portion.

5. A surgical device as claimed in any one of the preceding claims, in which a recess or projection is formed on the resilient arm and engages the first formation.

6. A surgical device as claimed in claim 5, in which the recess or projection is formed at a free end of the resilient arm.

7. A surgical device as claimed in any one of the preceding claims, in which the second portion is at least partially bifurcated.

8. A surgical device as claimed in claim 7, in which the resilient arm forms a fork of the bifurcated part of the second portion.

9. A surgical device as claimed in claim 7 or 8, in which the first formation is received between forks of the bifurcated part of the second portion.

10. A surgical device as claimed in any one of the preceding claims, in which the first portion is provided with a first planar guide surface which engages a second planar guide surface on the second portion.

11. A surgical device as claimed in any one of the preceding claims, further comprising an abutment which limits the relative movement between the first and second portions.

12. A surgical device as claimed in any one of the preceding claims, in which the first portion is adapted to connected, one at a time, to a plurality of alternative second portions.

13. A surgical device as claimed in any one of the preceding claims, in which the first portion comprises a surgical tool.

14. A surgical tool as claimed in claim 13, in which the first portion comprises a drill bit, broach, file or rasp.

15. A surgical device as claimed in claim 13 or 14, in which the first formation comprises an annular ridge formed around the circumference of the surgical tool.

16. A surgical device as claimed in any one of claims 13 to 15, in which the resilient arm is arcuate and curves at least partially around the circumference of the surgical tool.

17. A surgical device as claimed in any one of the preceding claims, in which the second portion is a handle.

18. A surgical device as claimed in any one of claims 1 to 12, in which the second portion comprises an adaptor to which a femoral head can be connected.

19. A surgical device as claimed in claim 18, in which a plurality of adaptors of different lengths and/or shapes are provided for attachment to the first portion.

20. A surgical device substantially as described herein, with reference to and as shown in the accompanying drawings.

ABSTRACT

SURGICAL DEVICE

A surgical device comprises a first portion 2 and a second portion 8, the first and second portions 2, 8 being releasably connected together by means of cooperating first and second formations 10, 12, the first formation 10 being formed on the first portion 2, and the second formation 12 comprising a resilient arm which is formed on the second portion 8 and engages the first formation on the first portion 2. Preferably, the resilient arm is integrally formed with the second portion.

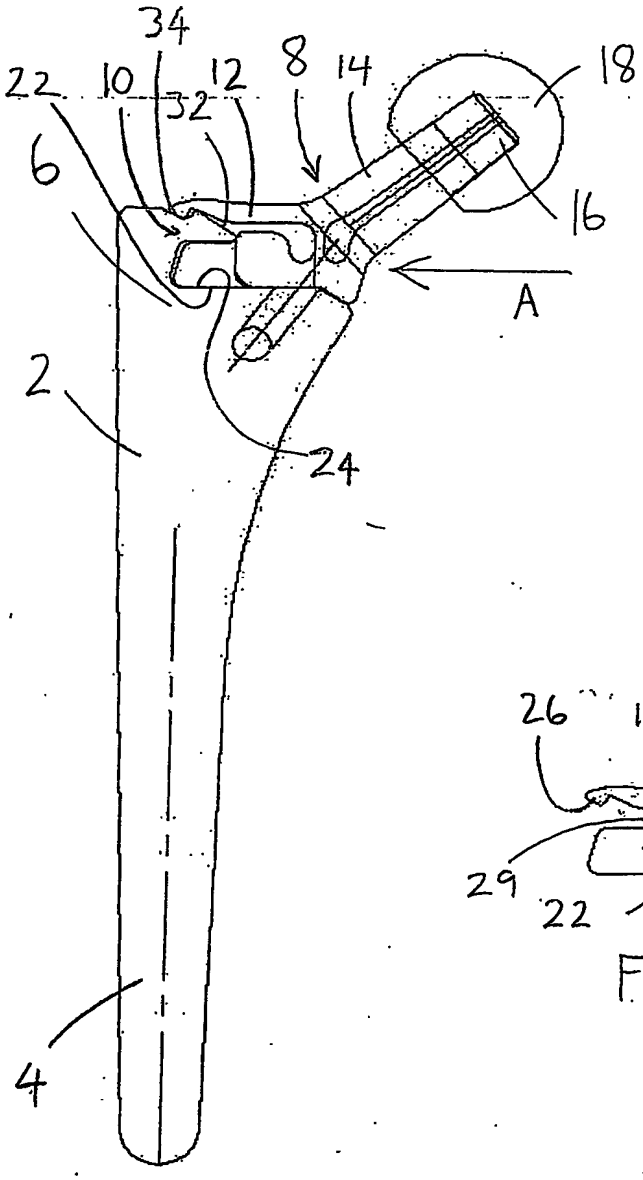

FIGURE 1

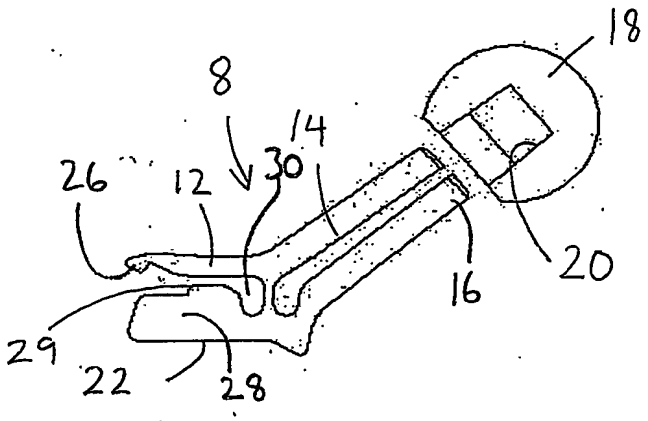

FIGURE 2